IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BARBARA MACK, as ADMINISTRATRIX of the ESTATE of WILLIAM A. MACK, JR., deceased, Plaintiff, v. VENTRACOR, INC., and THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, et. al., Defendants.	:	Civil Action No.: 10-cv-2142

DEFENDANT VENTRACOR, INC.'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION FOR REMAND AND FOR COSTS, EXPENSES AND FEES

COMES NOW, Defendant Ventracor, Inc. ("Ventracor"), by and through its undersigned counsel, Cozen O'Connor, and hereby opposes Plaintiff's Motion for Remand and for Costs, Expenses and Attorneys' Fees. In support, Ventracor adopts the arguments set forth in co-defendants' Memorandum of Law in Opposition to Plaintiff's Motion for Remand and additionally states as follows:

I. INTRODUCTION

The Trustees of the University of Pennsylvania (the "Hospital") and the individual physician defendants removed this case on the basis of three claims that Mrs. Mack brings related to an allegation of lack of informed consent; battery, fraudulent misrepresentation and breach of fiduciary duty (collectively, "Informed Consent claims"). These Informed Consent claims raise the question of whether a patient's consent to an experimental procedure is adequately informed if the patient is not fully apprised of his or her legal rights. Although plaintiff seeks to rely on Pennsylvania's Medical Care Availability and Reduction of Error (MCARE) Act, that Commonwealth law offers no guidance with respect to human test subjects

or the elements of a valid informed consent, and does not require any mention of a patient's legal rights when participating in a clinical study.

Federal law is the only place to find any suggestion that a patient's legal rights may be implicated when obtaining informed consent. Mrs. Mack recognized this in pursuing her previously filed (and voluntarily dismissed) action. In her earlier case, she relied exclusively upon federal regulations, such as 45 C.F.R. §46.116, 21 C.F.R. §50.20 and the "Common Rule," in alleging that the Hospital violated federal law when obtaining Mr. Mack's consent to the experimental procedure.

Now, in an effort solely designed to avoid the jurisdiction of this Court, Mrs. Mack brings precisely the same allegations, but artfully eliminates any reference to the federal law upon which she previously relied. Instead, she claims that Pennsylvania's MCARE Act controls. As discussed in greater detail below, MCARE has no bearing on determining the legal validity of Mrs. Mack's claims. Indeed, if MCARE does control the question of whether a patient is entitled to a full recitation of legal rights as part of informed consent, then the Court could easily dismiss these Informed Consent claims as there is no such basis for these novel causes of action in the statutes or common law of this Commonwealth.

No matter how it is plead, the relief plaintiff seeks in connection with her Informed Consent claims necessarily requires this Court to interpret and apply federal regulations. Once the Court clarifies the extent to which the federal regulations require a disclosure of patient legal rights as part of informed consent, then it must apply its interpretation of the federal law to the facts of this case to determine if the Hospital or the individual physician defendants breached that legally imposed duty here.

Consequently, to answer both the general question of legal duty and the specific factual question of whether the Hospital breached that duty, the Court must look to federal law. Despite

plaintiff's ability to cleverly plead around the applicable regulations, there is a strong need for these federal regulations to be interpreted and applied in a uniform manner. Thus, this Court may properly decide this case within its federal question jurisdiction.

II. BACKGROUND FACTS

A. The First Action against Ventracor, Inc.

The procedural history leading up to the removal of the instant matter is significant. Mrs. Mack first commenced her litigation on or about February 4, 2009 by filing a complaint in the Philadelphia Court of Common Pleas against the Trustees of the Hospital and Ventracor, Inc. See *Barbara Mack v. Ventracor, Inc., et al.*, February Term, 2009, No. 000633 (hereinafter, "First Action"). In that First Action, Mrs. Mack alleged state law claims, including strict liability, negligence, and breach of warranties. With respect to Ventracor, the First Action contained allegations against it as the designer, manufacturer, and seller of the VentrAssist device implanted in plaintiff's deceased husband, William A. Mack, Jr., for strict liability, negligence, and breach of warranty.

In response to the complaint in the First Action, the Hospital filed Preliminary Objections. Thereafter, Mrs. Mack filed eight additional amended complaints against the Hospital and Ventracor in an attempt to overcome the legal defects in her original and subsequent complaints. Defendants filed Preliminary Objections in response to most of those amended complaints.[1] To fully illustrate the extensive procedural history of the First Action, the state court's docket in *Barbara Mack v. Ventracor, Inc., et al.*, February Term, 2009, No.

[1] Ventracor filed preliminary objections beginning with the Third Amended Complaint. Neither defendant filed preliminary objections to the Fifth Amended Complaint because Plaintiff indicated she would be filing a Sixth Amended Complaint.

000633, and the federal court docket once the matter was removed are both attached hereto as Exhibit "A."

On February 19, 2010, more than one year after she filed her Original Complaint in the First Action, Mrs. Mack filed her Eighth Amended Complaint and, for the first time, asserted a cause of action for battery against the Hospital pursuant to 45 C.F.R. §46.116, the Code of Federal Regulations section addressing general requirements for informed consent. Mrs. Mack alleged that the Hospital, on behalf of itself and Ventracor, made material misrepresentations regarding her husband's legal rights as described in the informed consent form presented to Mr. Mack prior to his surgery. Mrs. Mack cited violations of 45 C.F.R. §46.116 and the "Common Rule," which apply to all "federally regulated and/or funded research performed at the University of Pennsylvania." (See Eighth Amended Complaint in First Action, attached as Exhibit "B" to the Hospital's Opposition to Remand).

In support of the battery claim she brought in the First Action, Mrs. Mack argued that the research involving Mr. Mack was not in compliance with the Hospital's Federal Wide Assurance ("FWA") which was submitted to the Office of Human Research Subject Protection of the U.S. Department of Health and Human Services. The FWA assures that research at the Hospital is conducted in compliance with federal regulations. The "Common Rule" cited by plaintiff refers to the cumulative effort of seventeen government agencies striving to promulgate consistent regulations for human research subjects across government.[2] The Rule was published in the Federal Register, which requires each governmental agency to administer the Rule uniformly through its regulations. See Note to 45 C.F.R. §46.

[2] Sub-part A of Title 45 of the Code of Federal Regulations, "Public Welfare," Part 46, "Protection of Human Subjects."

By her own admission, Count VIII of the Eighth Amended Complaint in the First Action implicated federal law.[3] Contending that federal question jurisdiction was invoked by plaintiff's battery claim in her Eighth Amended Complaint, defendants filed a timely Notice of Removal to federal court in the First Action on March 16, 2010. See Exhibit "A" hereto.

Faced with the reality of proceeding in federal court to litigate her Eighth Amended Complaint, Mrs. Mack quickly filed a Voluntary Dismissal and withdrew the First Action on March 26, 2010. Id.

B. The Instant Action

On March 31, 2010, five days after she voluntarily dismissed and withdrew the First Action, Mrs. Mack filed a nearly identical lawsuit in state court. The Complaint in the instant action pleads causes of action for battery, fraudulent misrepresentation and breach of fiduciary duty based on a lack of informed consent.

Determined to stay in state court, plaintiff removed any reference to federal authority in support of her otherwise identical battery claim in her new Complaint. Instead, she now purports to base her Informed Consent claims on the "strictures of the Medical Care Availability and Reduction of Error ["MCARE"] Act" of the Commonwealth of Pennsylvania. See Count VIII, Exhibit "A" to co-defendants' Opposition to Remand.

Despite her clever drafting, the Hospital and individual physicians removed the instant action on May 10, 2010 contending that Mrs. Mack nevertheless invoked federal jurisdiction by way of her battery claim.[4] On June 9, 2010, Plaintiff filed a Motion to Remand. On July 7, 2010, co-defendants filed their Opposition to Plaintiffs' Motion to Remand.

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[3] Where a program is federally established and thereafter is federally implemented, regulated, funded and controlled, the application or interpretation of the regulations invoke federal jurisdiction pursuant to §1331.

[4] Ventracor, Inc. was not a party to the action at that time. Attorneys for Ventracor, Inc. accepted service on its behalf on June 28, 2010.

Ventracor has been advised that this case is in civil suspension pending the outcome of plaintiff's pending remand motion. Therefore, believing the remand issue more time sensitive, Ventracor is filing this Brief in Opposition to Remand before filing a responsive pleading, which it intends to do in the near future. To avoid duplicative arguments and to conserve this Court's time and resources, Ventracor adopts and incorporates by reference the Opposition brief filed by the Hospital and individual physician defendants. The following argument is intended to supplement co-defendants' opposition, as additional support in opposition to Plaintiff's Motion to Remand.

III. LEGAL ARGUMENT

A. Plaintiff Seeks to Avoid Federal Jurisdiction by Omitting References to Controlling Federal Authority

It is obvious that Mrs. Mack wants to litigate this dispute in state court, which is her prerogative as master of her own complaint. However, she cannot ignore the fact that her battery claim against the Hospital can reside only under federal law no matter how she attempts to reframe it, and the Court's analysis necessarily requires interpretation and application of federal regulations.

In Count VIII of the Complaint, Mrs. Mack specifically takes issue with the following language in the informed consent form signed by her husband:

> Nothing in this informed consent shall act to waive any of your legal rights or to release the University of Pennsylvania Health System and School of Medicine, the study sponsor, Ventracor, Inc., or any of their agents from liability for negligence.

See Informed Consent Form at Exhibit "B" to Plaintiff's Complaint, attached to co-defendant's Opposition to Remand at Exhibit "A." Mrs. Mack's battery and other Informed Consent claims rest on the novel theory that the Hospital and Ventracor rendered the "no waiver" language in the

informed consent form a nullity by raising legal defenses in the First Action, such as preemption, by way of affirmative defenses and preliminary objections. The law Mrs. Mack seeks to enforce – prohibitions on exculpatory language – is only found in the FDA's guidelines as set forth in the Code of Federal Regulations, as follows:

> No informed consent, whether oral or written may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases the investigator, the sponsor, the institution, or its agents from liability for negligence.

See 21 C.F.R. §50.20. Insofar as the only legal basis for Mrs. Mack's Informed Consent claims is under federal regulations, these claims directly implicate federal question jurisdiction.

The Hospital presented the informed consent form to Mr. Mack in connection with his participation in a clinical trial involving the implantation of an experimental heart pump. That factual scenario fully distinguishes the Informed Consent claims at issue here from the "standard" informed consent dispute often litigated in state court. The consent form is an integral part of any FDA regulated research study. Where a human subject is involved in a clinical trial of an experimental drug or device, federal regulations directly address all aspects of informed consent. The C.F.R. provides the framework for informed consent for human subjects participating in clinical trials such as Mr. Mack. In addition to section 21 C.F.R. §50.20, other sections of the C.F.R. highlight the federal government's involvement, and interest, in regulating issues surrounding informed consent where human subjects are involved. Specifically, section 21 C.F.R. §50.25 provides detailed, multi-part regulations (the "eight basic elements") which describe the information that must be communicated to each subject participating in a clinical trial.

In an effort to avoid the clear federal implications of her claims, Mrs. Mack cast about for some state law that might support her Informed Consent claims and settled on the MCARE Act. Mrs. Mack's reliance on the MCARE statute is misplaced. MCARE does not apply to the

specifics of her Informed Consent claims here, which attack the content of the consent form presented to her husband. The law that applies to the content of the informed consent form, and in particular to a patient's legal rights, is found in federal regulations – the very same regulations that plaintiff plead the first time she brought a battery claim in her earlier Eighth Amended Complaint.

The absence of a direct citation to federal law on the face of her Complaint is not determinative. Just as Mrs. Mack relied so heavily upon federal regulations to support her battery claim in her Eighth Amended Complaint, so now do her Informed Consent claims implicate those same regulations even though she omitted them from her Complaint. The regulations haven't changed and plaintiff cannot alter the character of her battery claim by omitting the references to the Code of Federal Regulation (promulgated by the Food and Drug Administration and the Department of Health and Human Services) and other sources of federal authority in what is essentially her ninth amended complaint. *Guckin v. Deborah Nagle, et. al.*, 259 F.Supp. 2d 406, 410 (E.D. Pa. 2003).

Further, it is well known that the FDA regulates all aspects of the clinical trial. 21 C.F.R. §812.119. Indeed, the FDA closely reviews, approves, declines, supervises, monitors, corrects and enforces all aspects of the clinical trial process, beginning long before human subjects become involved or are asked to sign any consent forms. There is not a detail, including the informed consent form, that isn't regulated by the federal government when human subjects are involved in clinical trials.

It is simply illogical for Mrs. Mack to now argue that this <u>one</u> component of the clinical trial, the language of the informed consent form, is the <u>only</u> element of the entire process that is not regulated by the federal government, particularly when she made allegations in her Eighth Amended Complaint that informed consent was governed by federal regulations. Instead, she

now contends that her Informed Consent claims are controlled by some inapplicable provision in the MCARE Act, which does not address patient legal rights.

B. No Private Right of Action is Required for this Court to Exercise its Federal Jurisdiction

In support of Remand, Plaintiff argues that none of the federal regulations cited by the removing defendants invoke federal jurisdiction because none create a private right of action or remedy. As discussed in greater detail in co-defendants' memorandum of law in Opposition to Remand, it is clear that the opposite is true -- no private right of action is required for this Court to exercise its federal jurisdiction. Plaintiff simply ignores the controlling law on this point, *Grable & Sons Metal Products, Inc. v. Darue Engr'g & Mf'g*, 545 U.S. 308 (2005), citing *Merrell Dow Pharmaceuticals, Inc. v. Thompson,* 478 U.S. 804 (1986), and instead cites inapplicable cases which pre-date *Grable.*

As discussed in co-defendants' Opposition brief, the "Common Rule" cited by Plaintiff in support of her battery claim in her Eighth Amended Complaint evolved from an interest in uniform application and regulation of human research across government agencies. See 45 C.F.R. §46. This interest in uniformity is sufficient to warrant application of federal common law. *Boyle v. United Technologies Corp.,* 487 U.S. 500, 508 (1988)(where the federal interest requires a uniform rule, the entire body of state law applicable to the area conflicts and is replaced by federal rules); *United States v. Kimbell Foods*, 440 U.S. 715, 728 (1979)(federal programs that by their nature are and must be uniform throughout the nation necessitate formulation of federal rules); *Clearfield Trust Co. v. United States*, 318 U.S. 363 (1943)(applying federal common law because the "desirability of a uniform [federal] rule is plain").

More recently, the Second Circuit fully analyzed informed consent in the context of human research in *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163 (2nd Cir. 2009). *Abdullahi* makes clear that the matter of informed consent in human research is of such universal concern that it

surpasses domestic law and becomes a matter of customary, international law. Writing for the majority, Judge Parker held:

> [This] history illustrates that from its origins with the trial of Nazi doctors at Nuremberg through its evolution in international conventions, agreements, declarations and domestic laws, the norm prohibiting nonconsensual medical experimentation on human subjects has become firmly embedded and secured universal acceptance in the community of nations.

Abdullahi, 562 F.3d 163, 183 (2009).

As shown, there is an abundance of federal authority which makes clear the federal government has a strong interest in regulating research involving human subjects, both because the matter invokes "universal concern" and to ensure consistency in regulation and enforcement. No matter how many times she amends and recasts it, Ms. Mack's Informed Consent claims arise under federal law because they are related to the testing of human subjects, conferring jurisdiction with this Court.

IV. CONCLUSION

For the reasons set forth in co-defendants' Memorandum of Law in Opposition to Remand and herein, Defendant Ventracor, Inc., opposes Plaintiff's Motion to Remand and respectfully requests that the Court deny Plaintiff's Motion and retain this matter arising under federal law pursuant to 28 U.S.C. 1331.

Respectfully submitted,

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Date: July 9, 2010

CERTIFICATE OF SERVICE

Terry M. Henry, Esquire, hereby certifies that on this date he caused to be served a true and correct copy of Defendant Ventracor, Inc.'s Response to Plaintiff's Motion for Remand by U.S. First-Class Mail upon counsel listed below:

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